

Message Text

UNCLASSIFIED

PAGE 01 STATE 005211
ORIGIN HEW-06

INFO OCT-01 AF-08 ARA-10 EUR-12 NEA-10 ISO-00 OES-06 /053 R

DRAFTED BY DHEW/FDA: JRWEINROTH,M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: BROYSTER

ARA/EX:CJACO0INI (INFO)

AF/EX:JTIERNEY (INFO)

NEA/EX:EGABINGTON (INFO)

EUR/EX:JLTULL (INFO)

-----110418Z 130887 /63

P 102240Z JAN 77

FM SECSTATE WASHDC

TO AMCONSUL SAO PAULO PRIORITY

AMEMBASSY KINSHASA PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY LONDON PRIORITY

AMEMBASSY BONN PRIORITY

AMEMBASSY TEHRAN PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY BERN PRIORITY

AMEMBASSY LA PAZ PRIORITY

AMEMBASSY CARACAS PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BR, CG, ES, UK, GW, IR, IT, SP,

SZ, BL, VE

SUBJECT: SUB-POTENT IN-VITRO ANTIBIOTIC SENSITIVITY
DISC (RECALL D-059-7)

1. FDA ADVISES OF THE FOLLOWING PRODUCT RECALL:

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PRODUCT INVOLVED: OXACILLIN SENSITIVITY DISC, 1MCG.

STRENGTH, LABELED AS FOLLOWS: DIFCO DISPENS-O-DISC,

DIFCO LABS, DETROIT, MICHIGAN. THE PRODUCT IS PACKAGED

50 DISCS PER MAGAZINE, SOLD AS EITHER SINGLE MAGAZINES OR

6 MAGAZINES PER CARTON. THE PRODUCT IS USED AS AN IN-VITRO

ANTIBIOTIC SENSITIVITY DISC FOR CLINICAL LABORATORY USE.

PRODUCT IS LABELED AS ABOVE WITH INFORMATION INDICATING

EXPIRATION DATE XXX STORE AT 2-8 DEGREES C. XXX LOT NO. XXX
DIFCO LABORATORIES, DETROIT, MICHIGAN USA. LABEL ON THE
CARTON OF 6 MAGAZINES IS SEEN AS THE FOREGOING EXCEPT IT
ALSO LISTS "6 MAGAZINES, 50 DISCS EACH. A INSERT IS
INCLUDED WITH THE PRODUCT AND IS A STANDARD INSERT FOR
ALL ANTIBIOTIC SENSITIVITY DISCS WHICH READS IN PART
"BACTO-SENSITIVITY DISCS. ANTIBIOTIC SUSCEPTIBILITY DISCS
FOR USE IN THE STANDARDIZED ANTIBIOTIC DISC SUSCEPTIBILITY
TEST XXX DIFCO LABS, DETROIT, MICHIGAN. JANUARY 1976".

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LOT NOS:

PRODUCT CODE	PACKED	CONTROL NO.
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6351-90-3	1 MAGAZINE	620965
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6351-91-2	6 MAGAZINE	618241
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6351-91	6 MAGAZINE	625841
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(EXPORTED ONLY)

ALL OF THE THREE ABOVE CONTROL NUMBERS ARE BEING RECALLED
BECAUSE THEY WERE PACKAGED FROM THE SAME BULK BATCH.

MANUFACTURER/RECALLING FIRM:

DIFCO LABORATORIES, 920 HENRY STREET, DETROIT, MICHIGAN.

2. REASON FOR RECALL:

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ON 8 OCTOBER 1976 THE FIRM RECEIVED A USP LABORATORY
PRODUCT PROBLEM REPORT NUMBER D-2214 WHICH REPORTED
THAT OXACILLIN DISCS OF THE ABOVE MENTIONED LOT GAVE
ERRATIC RESULTS UPON USE. ASSAYS WERE PERFORMED BY
THE FIRM AND THE FDA. THE ASSAY RESULTS INDICATED
MARGINAL TO LOW POTENCY. RECALL WAS INITIATED BY LETTER
DATED 10 NOVEMBER 1976. FOREIGN CONSIGNEES WERE INST-
RUCTED TO NOTIFY THEIR CUSTOMERS TO RETURN THE STOCK ON
HAND TO DIRECT ACCOUNT AND THE DIRECT ACCOUNT WAS
INSTRUCTED TO DESTROY ANY STOCK ON HAND OR RETURNS FROM
CUSTOMERS AND ADVISE DIFCO OF THE NUMBER OF UNITS DES-
TROYED.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE RECALL.
ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE DIRECTED TO
THE FIRM. CONTACT AT THE FIRM IS MR. HERMAN NELSON,
VICE PRESIDENT, TELEPHONE 313-961-0800.

4. FOREIGN CONSIGNEES AS FOLLOWS:

INTERLAB
RUA LUIZ GOES 684
VILA MARIANA
CAIXA POSTAL 15192
SAO PAULO, BRAZIL

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DROGUERIA Y
DISTRIBUIDORA MARIN
SAN SALVADOR, EL SALVADOR

OTTO NORDWALD KG
HEINRICHSTRASSE 5
HAMBURG 50, GERMAN

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M/S WIDAL CO., LTD.
59 AVE SHAHREZA
KAKH CROSS
TEHRAN, IRAN

MARTIN HISPANICA
CASTELLO 109
MADRID, SPAIN

FOMECO
HOSPITAL MM YEMO
BP 169
KINSHASA, REPUBLIC DU ZAIRE

DIFCO LABORATORIES
P O BOX 14 B/CENTRAL AVE.
EAST MOLESEY
SURREY KT 8. OSE
ENGLAND

BIOTEST SERUM INSTITUTE
POSTFACH 730260
6 FRANKFORT /MAIN 73
WEST GERMANY

DIFCO SAS
PLAZZA C AMATI 6
20147 MILAN
ITALY

CHEMIE BRUNSCHWIG AG

P O BOX 250
CH-4009 BASEL
SWITZERLAND

LABORATORIO INDUSTRIALES
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GUZMAN LTDA
CASILLA 6240
LA PAZ, BOLIVIA

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CENCO ZOTTI CIENTIFICA SA
APARTADO 80252
CARACAS 108
VENEZUELA
KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: PRODUCTION CONTROLS, BACTERIA, EXPORT DATA, LABORATORIES
Control Number: n/a
Copy: SINGLE
Sent Date: 10-Jan-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE005211
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH,M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770009-1036
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770165/aaaacfp.tel
Line Count: 191
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 24e9b6db-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 15-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3630497
Secure: OPEN
Status: NATIVE
Subject: SUB-POTENT IN-VITRO ANTIBIOTIC SENSITIVITY DISC (RECALL D-059-7)
TAGS: OGEN, ETRD, TBIO, XF, XG, XL, XJ
To: SAO PAULO KINSHASA MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/24e9b6db-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009